DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

[Docket Nos. 2005M–0320, 2005M–0289, 2005M–0387, 2005M–0270, 2005M–0379, 2005M–0388, 2005M–0284, 2005M–0283, 2005M–0328, 2005M–0308, 2005M–0380, 2005M–0321, 2005M–0339, 2005M–0359, 2005M–0382, 2005M–0381, 2005M–0378]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

NAD 1

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register.**

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2005, through September 30, 2005. There were no denial actions during

this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2005, THROUGH SEPTEMBER 30, 2005

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P040043/2005M–0320	W.L. Gore & Associates, Inc.	GORE TAG THORACIC ENDOPROSTHESIS	March 23, 2005
P030035(S3)/2005M–0289	St. Jude Medical	FRONTIER MODEL 5508L AND FRONTIER II MODEL 5586 CARDIAC RESYNCHRONIZATION THERAPY PACEMAKERS (CRT-P) SUPPORTED ON THE MODEL 3510 PROGRAMMER PLATFORMS WITH THE MODEL 3307, V4.8M PROGRAMMER SOFTWARE	April 29, 2005
P040005/2005M–0387	DakoCytomation Denmark A/S	DAKOCYTOMATION HER2 FISH PHARMDX KIT	May 3, 2005
P030049/2005M–0270	Bayer Healthcare, LLC	ADVIA CENTAUR HBSAG READY PACK REAGENTS/CONFIRMATORY READY PACK REAGENTS/QUALITY CONTROL MATERIAL	May 26, 2005
P040037/2005M–0379	W.L. Gore & Associates, Inc.	VIABAHN ENDOPROSTHESIS	June 14, 2005
P040011/2005M–0388	DakoCytomation California, Inc.	DAKOCYTOMATION C-KIT PHARMDX	June 27, 2005
P950042(S3)/2005M–0284	Xillix Technologies Corp.	ONCO-LIFE ENDOSCOPIC LIGHT SOURCE AND VIDEO CAMERA	June 30, 2005
P970003(S50)/2005M–0283	Cyberonics, Inc.	VNS THERAPY SYSTEM	July 15, 2005
P030004/2005M–0328	Micro Therapeutics, Inc.	ONYX LIQUID EMBOLIC SYSTEM	July 21, 2005
H050001/2005M–0308	Boston Scientific Smart	WINGSPAN STENT SYSTEM WITH GATEWAY PTA BALLOON CATHETER	August 3, 2005
P030036/2005M–0380	Medtronic, Inc.	MEDTRONIC SELECTSECURE	August 3, 2005
P040021/2005M–0321	St. Jude Medical, Inc.	SJM BIOCOR VALVE/SJM BICOR SUPRA VALVE	August 5, 2005
P040039/2005M–0339	Orthometrix, Inc.	ORBASONE PAIN RELIEF SYSTEM	August 10, 2005
P040044/2005M–0359	Access Closure, Inc.	MATRIX VSG SYSTEM MODEL MX–100	August 17, 2005
P930016(S21)/2005M–0382	Visx, Inc.	STAR S4 IR EXCIMER LASER SYSTEM WITH VARIABLE SPOT SCANNING (VSS)	August 30, 2005
P040038/2005M–0381	Abbott Vascular Devices	XACT CAROTID STENT SYSTEM	September 6, 2005
P930014(S15)/2005M–0378	Alcon Laboratories	ACRYSOF TORIC POSTERIOR CHAMBER INTRAOCULAR LENS	September 14, 2005

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: 12/20/05

December 20, 2005.

Linda S. Kahan

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